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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,124	07/28/2005	Gerard Devauchelle	033339/287318	1945

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,124	DEVAUCHELLE ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/24/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Objections to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Specifically, a hyperlink is present on page 1 of the specification.

The disclosure is objected to because it does not contain a Brief Description of the Drawings section. When drawings are present in an application, the specification **shall contain** a Brief Description of the Drawings (See MPEP 608.01(f)).

Sequence Rules

The Sequence Listing filed 7/28/07 was submitted without an amendment specifically directing entry of the paper copy of the Sequence Listing into the specification. Applicants are required to submit a paper copy of the Sequence Listing accompanied by an amendment directing entry of the Sequence Listing into the specification. Any response that does not fully comply with the Sequence Rules will be considered non-responsive.

35 USC 103(a) Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-4, 8, 9, 11, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. in view of Ginns et al. and Rasmussen et al.

Applicants claim an expression cassette comprising: a) a promoter derived from the polyhedrin promoter of a baculovirus by deletion of all or part of the region of said promoter extending from positions -1 to -12 relative to the polyhedrin translation initiation site; b) a sequence encoding a receptor with seven transmembrane domains (i.e. an olfactory receptor), placed under the transcriptional control of said promoter. Applicants also claim a recombinant baculovirus comprising said expression cassette and an insect cell comprising said baculovirus as well as a method for expressing said receptor, determining the functionality of a putative receptor with seven transmembrane domains and identifying receptors capable of binding to a ligand of interest.

Gat et al. (cited by applicants, Eur. J. Biochem., 1994, Vol. 225, pp. 1157-1168, see whole article, particularly the Abstract; p. 1159, right column; p. 1164 and pp. 1166-

1167) teaches an expression cassette in the context of a recombinant baculovirus and insect cells comprising said baculovirus and expressing the receptor, wherein the claims also recite a method for expressing the receptor in the insect cells and wherein the transfected recombinant insect cells are used to identify an olfactory receptor (which is capable of binding to a ligand of interest) through analysis of size, glycosylation, membrane insertion, etc. of said receptor expressed by the insect cells. Gat et al. does not teach use of a promoter derived from the polyhedron promoter by deletion of all or part of the region of said promoter extending from positions -1 to -12 relative to the polyhedrin translation initiation site in the expression cassette.

Ginns et al. (US 5,879,680, issued 3/9/99, see whole document, particularly Fig. 2, columns 2 and 3) teaches use of the pAc373 transfer vector to generate recombinant baculoviruses capable of expressing a transgene (glucocerebosidase) operably linked to a modified polyhedron promoter.

Rasmussen et al. (US 5,236,838, issued 8/17/93, see whole document, particularly column 7, lines 48-62) teaches that a standard baculoviral expression vector (pAc373) contains a deletion of the polyhedron promoter to position –8 relative to the polyhedron translation start codon.

The ordinary skilled artisan, seeking to generate recombinant baculoviruses which express sequences encoding a receptor with seven transmembrane domains (for example, an olfactory receptor) and use cells infected with said baculoviruses and expressing said receptors to identify and characterize said receptors would have been motivated to combine the teachings of Gat et al. on the generation and use of

recombinant baculovirus vectors which express an olfactory receptor with seven transmembrane domains so as to identify and characterize said receptor with the teachings of Ginns et al. on use of a recombinant baculovirus generated using a transfer vector (pAc373) which comprises a modified polyhedron promoter deleted for positions –1 to –8 relative to the polyhedron translation start codon (as evidenced by Rasmussen et al.) because recombinant baculoviruses generated using the pAc373 transfer vector were among the first recombinant baculovirus vectors generated (almost 20 years ago) and are among the most widely used baculovirus vectors for expression of heterologous genes (almost 1,000 patents recite use of this vector or variants of said vector). It would have been obvious for the ordinary skilled artisan to generate baculovirus vectors capable of expressing an olfactory receptor (as taught by Gat et al.) with a deletion of part or all of the polyhedron promoter sequence extending from positions –1 to –12 relative to the polyhedron translation initiation site because recombinant baculovirus vectors generated using transfer vectors such as pAc373 (containing a deletion of the region from –1 to –8) were among the most widely used recombinant baculovirus expression vectors. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 2 and 16-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. in view of Ginns et al., Rasmussen et al. and Murphy et al.

Applicants' invention is as described above. In addition, applicants recite that the expression cassette comprises a sequence encoding a signal peptide upstream of the sequence encoding the receptor.

Gat et al. Ginns et al. and Rasmussen et al. are applied as above. None of these references explicitly teaches a sequence encoding a signal peptide upstream of the sequence encoding the receptor.

Murphy et al. (US 5,516,657, issued 5/14/96, see whole document, particularly the Abstract and "Detailed Description of the Invention" section in columns 5-7, Claims 1-18) teaches that signal sequences derived from baculoviruses can be positioned downstream of the polyhedron promoter and upstream of the coding sequence of interest and said signal sequences improve expression of the heterologous protein of interest by efficiently processing the recombinant protein through the cell's endoplasmic reticulum.

The ordinary skilled artisan, seeking to improve expression and processing of heterologous proteins expressed using recombinant baculoviral vectors in insect cells, would have been motivated to modify the baculoviral vectors taught by the Gat et al. Ginns et al. and Rasmussen et al. references by including a sequence encoding a baculoviral signal peptide upstream of the coding sequence of the protein of interest and downstream of the polyhedron promoter because Murphy et al. teaches that inclusion of such a signal sequence improves expression and processing of heterologous genes expressed by the cells infected with the recombinant baculoviral vectors. It would have been obvious for the ordinary skilled artisan to include a

baculoviral signal sequence in the recombinant baculoviral vectors disclosed by the combination of Gat et al., Ginns et al. and Rasmussen et al., because the signal sequences are being used for their known and expected properties, i.e. to improve expression and processing of the heterologous gene products operably linked to said signal sequences. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 5-7, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gat et al. in view of Ginns et al. and Rasmussen et al. and further in view of Ames et al. and Meyer et al.

Applicants' invention is as described in the above 102(b) rejection over Gat et al. in view of Ginns et al. and Rasmussen et al. In addition, applicants claim expression of a sequence encoding a G protein operably linked to the promoter of a p10 gene of a baculovirus and use of insect cells infected with a baculovirus comprising an expression cassette comprising said sequence encoding the G protein under control of the p10 promoter for identification of orphelin receptors with seven transmembrane domains.

Gat et al., Ginns et al. and Rasmussen et al. are as described above. None of these references teach expression of a sequence encoding a G protein operably linked to the promoter of a p10 gene of a baculovirus and use of insect cells infected with a baculovirus comprising an expression cassette comprising said sequence encoding the

G protein under control of the p10 promoter for identification of orphelin receptors with seven transmembrane domains.

Ames et al. (US 6,433,156, issued 8/13/02, filed 12/22/98, see whole document, particularly the Abstract; columns 1-2 and 7-10) teaches that co-expression of G-protein coupled receptors and G-proteins is often necessary for the cells to express the full biological activity of the receptors and that co-expression of the receptors and G proteins can be accomplished using baculoviral vectors. Ames et al. also teaches that the expressed receptors (which can be orphelin receptors) can be used to identify ligands for said receptors. Ames et al. does not teach specific baculoviral vectors capable of expressing the receptor gene and G-protein gene.

Meyer et al. (US 6.057,143, issued 5/2/00, filed 7/17/97, see whole document, particularly Fig. 3; Examples 1-4) teaches the generation of recombinant baculoviral vectors which express two different proteins, one under control of the polyhedron promoter and one under control of the baculoviral p10 promoter.

The ordinary skilled artisan, seeking to co-express a receptor with seven transmembrane domains and a G-protein would have been motivated to combine the teachings of Gat et al., Ginns et al. and Rasmussen et al. on the generation of recombinant baculoviruses capable of expressing receptors with seven transmembrane domains using a polyhedron promoter deleted of part of the sequence –1 to –12 relative to the polyhedron translation initiation site with the teachings of Ames et al. on the desirability of co-expressing (using a baculoviral vector) a G-protein coupled receptor (having seven transmembrane domains) with a G-protein so as to express the full

biological activity of the receptors further with the teachings of Meyer et al. on the generation and use of baculoviral vectors which express two different sequences using the polyhedron and p10 promoters because Ames et al. teaches that full biological activity of expressed seven transmembrane domain receptors is achieved when they are co-expressed (using a baculoviral vector) with the relevant G protein and that baculoviral vectors capable of co-expressing two different nucleic acids of interest are readily available in the art (Meyer et al.). It would have been obvious for the ordinary skilled artisan to co-express a receptor with seven transmembrane domains and a relevant G protein using a bi-functional recombinant baculovirus vector because Ames et al. teaches that co-expression (using a baculoviral vector) of the receptor and the relevant G-protein are necessary for biological activity of the receptor and Meyer et al. teaches that bi-functional baculoviral vectors which express two different proteins, one from the polyhedron promoter and one from the p10 promoter can be used to express two different heterologous proteins. With regard to use of the expressed receptors to identify ligands for orphelin receptors, Ames et al. specifically teaches that co-expression of putative receptors and G-proteins can be used to identify the functions of receptors and identify ligands for said receptors. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

35 USC 112, 2nd Paragraph/35 USC 101 Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-15 provide for the use of insect cells, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 12-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID GUZO
PRIMARY EXAMINER

David Guzo
August 1, 2007